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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,158	03/29/2004	Emmanuel Delorme	2003456-US	8473

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COLOPLAST CORP.
I.P. DEPARTMENT, U.S. OPERATIONS
P.O. BOX 580800
MINNEAPOLIS, MN 55456-0800

EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3771	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,158	DELORME ET AL.	
	Examiner	Art Unit	
	SHUMAYA B. ALI	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/20/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,36-39,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,36-39,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-21, 23-25, and 40 are cancelled. Claims 22, 36-39, 41, and 42 are pending in the instant application.

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Drawings

The drawings are objected to because two orifices are not labeled. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the posterior stabilizers of an anterior prosthesis must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 36,37,38, and 39 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Cited

claims fail depends from cancelled claims, thus, fails to further limit the subject matter of a previous claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22,36-39,41, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 22, 41, and 42, lines 2 and 3, the recitation of "the implant presenting a structure that is thin and flexible and comprising a support body "is indefinite. It is not clear whether the support body and rest of the claimed recitation are directed to the "implant" or the "thin and flexible". In lines 7 and 8 the "posterior stabilizers of an anterior prosthesis" is indefinite. It appears there is an anterior stabilizer required, however, location of the anterior stabilizers of an anterior prosthesis is not clear. It is not clear whether this structure is part of the implant. Furthermore, exact structure of posterior stabilizers of an anterior prosthesis is not clear. In line 8 "stabilizer have passed though the uterosacral ligament" is using human body as reference points. Applicant is strongly suggested to use adapted to language when describing position of the implant with respect to the human body.

In claim 38 line 4 "middle suspension stabilizers" lack antecedent basis.

In claim 39 lines 1 and 2 "the upper portion of the implant" lacks antecedent basis.

In claim 41 lines 6 "in part" is indefinite. It is not clear whether the rest of the parts are also made from one of the biocompatible materials listed in lines 7-9. Specification does not clearly state only a part of the implant is made from claimed biocompatible material. It is not clear whether two parts ("in part" and rest of the parts) would be same material or different material.

In claim 42 lines 6 "further characterized" is indefinite. It is not clear whether the recitation referring back to the "implant" in line 1 or "thin and flexible" in line 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 36-39, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacquetin US 7,131,944 B2 in view of Gellman WO 98/35632.

As to claim 22, Jacquetin discloses an implant in figures 1-11. In column 2 lines 50-54 Jacquetin discloses material for the implant being bio-compatible mesh material such as a knitted polypropylene fabric (e.g., soft PROLENE...). This soft nature of the fabric allows the implant to be adapted to be placed in the vaginal fornix to treat rectocele and/or prolapsus. Jacquetin in column 2 lines 6 and 7 further discloses the implant is for treating rectocele and/or a hysterocele present in a female patient. Jacquetin in column 2 lines 50 and 51 discloses the implant is made from a single sheet of mesh material, which makes the implant thin, and in column 3 lines 9 and 10 Jacquetin discloses the implant can be sized and shaped to meet the need of a particular patient. Being able to size and shape the implant make the implant flexible. Figure 10 shows a support body (112/114) from which there extend suspension stabilizers (142 and 144). Figure 10 further shows at least two upper suspension stabilizers which are disposed on either side of a sagittal plane and have longitudinal axes forming between them an angle greater than 45 degrees, and two lower suspension stabilizers disposed on either side of the sagittal plane.

Jacquetin however lacks wherein the implant body presents, in its upper region, at least two orifices for passing posterior stabilizers of an anterior prosthesis once the stabilizers have passed though the uterosacral ligaments. However, Gellman in a urethral suspension slings/implant teaches a body (12) with upper region having two orifices (18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Jacquetin in order to provide the body with two orifices at the upper region for the purposes of providing suture receiving sites as taught by Gellman (see page 7 line 19).

As to claim 36, Jacquetin discloses the implant as applied for claim 22. Jacquetin however does not explicitly teach the location of the upper and lower stabilizers as claimed. However, Jacquetin in column 3 lines 9 and 10 discloses the implant can be modified by the surgeon to accommodate different patients. Furthermore, it would have been obvious to one of ordinary skill in the art to place the stabilizers at the treatment site, and for rectocele or prolapsus of the vaginal fornix it would have been obvious to one of ordinary skill in the art to place the implant such to cover gluteal, pubo-rectal, and uterosacral region since these areas are likely to be herniated/protruded in patients who are diagnosed with rectocele. Therefore, the step of placing the upper suspension stabilizers though the gluteal region, the lower suspension stabilizers though the pubo-rectal region and the support body in the uterosacral region would have been obvious to one of ordinary skill in the art when treating a patient with rectocele.

As to claim 37, Jacquetin discloses the implant as applied for claim 22. Jacquetin however does not explicitly teach the location of the upper and lower stabilizers as claimed. However, as applied for claims 22 and 36, Jacquetin's implant can be modified by the surgeon to accommodate different patients. Furthermore, it would have been obvious to one of ordinary skill in the art to place the stabilizers at the treatment site, and for rectocele or prolapsus of the vaginal fornix it would have been obvious to one of ordinary skill in the art to place the implant such to cover sacrosciatic, pubo-rectal, and uterosacral regions since these areas are likely to be herniated/protruded in patients who are diagnosed with rectocele. Therefore, the step placing the upper suspension stabilizers though the sacrosciatic region, the lower suspension stabilizers through the pubo-rectal

region, and the support body in the uterosacral region would have been obvious to one of ordinary skill in the art when treating a patient with rectocele.

As to claim 38, Jacquetin Jacquetin discloses the implant as applied for claim 22. Jacquetin lacks the middle suspension stabilizers. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the middle stabilizer, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.,* 193 USPQ8.

Jacquetin further does not explicitly teach the location of the upper and lower stabilizers as claimed. However, as applied for claims 36 and 37, Jacquetin's implant can be modified by the surgeon to accommodate different patients. Furthermore, it would have been obvious to one of ordinary skill in the art to place the stabilizers at the treatment site, and for rectocele or prolapsus of the vaginal fornix it would have been obvious to one of ordinary skill in the art to place the implant such to cover sacrosciatic, pubo-rectal, perineal regions, and rectovaginal septum since these areas are likely to be herniated/protruded in patients who are diagnosed with rectocele. Therefore, the step placing the upper suspension stabilizers though the sacrosciatic region, the middle stabilizers though the pubo-rectal region, the lower suspension stabilizers through the perineal region, and the support body in the rectovaginal septum would have been obvious to one of ordinary skill in the art when treating a patient with rectocele.

As to claim 39, Gellman teaches posterior stabilizers of an anterior prosthesis as sutures that is received by orifices (18) on the body (see col.7 line 19). These sutures passing though the orifices (18) at the upper portion of the implant allow support the

upper portion of the implant. Sutures of Gellman are acting as the posterior stabilizers of an anterior prosthesis.

As to claim 41, Jacquetin/Gellman teaches the claimed invention as applied for claim 22. Jacquetin in column 2 lines 51-54 further teaches claimed biocompatible material.

As to claim 42, Jacquetin/Gellman teaches the claimed invention as applied for claim 22. Jacquetin in figure 10 shows the implant is substantially flat and hammock-like.

Response to Arguments

Applicant's arguments with respect to claim 22, 36-39, 41, and 42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Prior art made of record not relied upon cited in the PTO form 892 pertain to pelvic organ implants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHUMAYA B. ALI whose telephone number is (571)272-6088. The examiner can normally be reached on M-W-F 9 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shumaya B. Ali /
Examiner, Art Unit 3771
February 7, 2008

/Teena Mitchell/
Primary Examiner, Art Unit 3771